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10/582,869

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Bernd Hansen

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08/13/2008

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EXAMINER

TRUONG, THANH K

ART UNIT

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3721

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/582,869 | Applicant(s) HANSEN, BERND | |
| | Examiner THANH K. TRUONG | Art Unit 3721 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to applicant's amendment received on April 24, 2008.
2. Applicant's cancellation of claims 1-11 is acknowledged.
3. New claims 12-26 are pending in the application.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14, the phrase "a specified over-pressure" is vague and indefinite, because it is unclear what is the term "a specified over-pressure" comprised? - It is unclear at what pressure is "a specified over-pressure" being referred to?

6. Examiner's note: reference US 2004/0065983 A1 is being use as an English translation for the (DE 10063282 C2).

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 12-14 and 17-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansen et al. (DE 10063282 C2).

Hansen et al. discloses an apparatus (as in claim 24) and a method (as in claim 12) comprising: at least one tube (3) of softened plastic material is extruded into an opened mold (6), the tube is closed at its projecting end when the mold (6) is closed to form the bottom of the container, the tube is separated above the mold by means of a separating element (21) to form a filler opening (15), and the mold is moved with the tube having the filler opening into a filling position in which the container, after it has been formed by generation in the mold of a pressure gradient acting on the tube and expanding it, is filled and then sealed (figures 1-2), the filler opening of the tube being covered by a sterile barrier (23) at least from the time of its formation to that of filling of the respective container, wherein by means of the sterile barrier (23) at least one sterile medium (it is construed that the heated plate heats the surrounding air, and the hot air is the sterile medium) is moved in the direction of the filler opening (15) by means of a media delivery device (23).

Hansen et al. further discloses:

Regarding claims 13 and 14, wherein the sterile medium is air; and the sterile medium is conveyed at a specified pressure in the direction of the filler opening (it is construed that the medium being conveyed to cover the filler opening, therefore it is under a specified pressure, because without pressure different, there would not be any movement of the medium).

Regarding claims 17 and 25, the sterile barrier is configured as a plate-shaped cover element (23) which, after separation of the tube, covers the filler opening and provides it with a sterile medium until filling of the container is undertaken after its expansion below the sterile filling space (as mention above, it is construed that heated air is the sterile medium).

Regarding claim 18, the cover element (23) moves together with the separating element (21) for separation of the plastic tube.

Regarding claim 19, the cover element moves synchronously with parts of the mold, and does not clear the filler opening until filling of the container (US 2004/0065983 - [0022], lines 1-8)

Regarding claims 20 and 21, wherein the container is rinsed by or partly filled with the respective medium by means of the media delivery device (23), by way of the filler opening (as mention above, it is construed that heated air is the sterile medium).

Regarding claims 22 and 23, wherein the sterile barrier and/or the sterile medium are heatable, by preference to a temperature higher than 120 degrees C, by preference to a temperature situated within the range of 150 to 200 degrees C (see claim 4).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 15, 16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen et al. (DE 10063282 C2) in view of Zelina et al. (US 2002/0159915 A1).

As discussed above, Hansen et al. discloses the claimed invention, but it does not expressly disclose that a suction device in the form of a vacuum device.

Zelina et al. discloses an apparatus and a method in which the sterile medium is hydrogen peroxide ([0035] page 2) and a suction device in the form of a vacuum device (112) is used (figure 1) to provide means to sterilize and decontamination the sterile filling space (abstract).

Therefore, it would have been obvious to one having ordinary skill in the art, at the time applicant's invention was made, to have modified Hansen et al. by incorporating the use of sterile medium and vacuum device as taught by Zelina et al. to provide means for sterilizing and decontamination the sterile filling space to achieve the condition as recited in claims 15, 16 and 26.

In light of the Applicant's amendment filed April 24, 2008 (new claims 12-26), following is the 102(b) rejection:

11. Claims 12-14 and 17, 20 and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Furui Koichi (JP 60049919 A).

Furui Koichi discloses (Figs. 1-3) an apparatus and a method comprising: at least one tube (6) of softened plastic material is extruded into an opened mold (8), the tube is closed at its projecting end when the mold is closed to form the bottom of the container, the tube is separated above the mold by means of a separating element to form a filler

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opening (not number), and the mold is moved with the tube having the filler opening into a filling position (Fig. 3) in which the container, after it has been formed by generation in the mold of a pressure gradient acting on the tube and expanding it, is filled and then sealed (Figs. 3a-c), the filler opening of the tube being covered by a sterile barrier (12) at least from the time of its formation to that of filling of the respective container, wherein by means of the sterile barrier at least one sterile medium (aseptic pressure air - abstract) is moved in the direction of the filler opening by means of a media delivery device (abstract in English).

Regarding claims 13 and 14, wherein the sterile medium is air; and the sterile medium is conveyed at a specified pressure in the direction of the filler opening (Figs. 3a-c).

Regarding claims 17 and 25, the sterile barrier is configured as a plate-shaped cover element (it is construed that device 12 comprises plates that formed the device) which, after separation of the tube, covers the filler opening and provides it with a sterile medium until filling of the container is undertaken after its expansion below the sterile filling space.

Regarding claim 20, the container (14) is flushed across the filler opening by the sterile medium by the media delivery device.

Regarding claims 22 and 23, it is construed that since Furui Koichi discloses that the medium is aseptic pressure air, it anticipated the temperature requirement (as recited in claim 22 and 23) so that the air is qualified as aseptic air.

Response to Arguments

12. Applicant's arguments filed April 24, 2008 have been fully considered but they are not persuasive.

13. In response to the Applicant's argument that:

"To the extent that heated air may be generated by the heated plate 23, such heated air, being of lighter weight than the surrounding ambient air, will move upwardly in a direction away from the fill openings in a manner similar to hot air in a balloon. Any heated air surrounding the Hansen German patent plate 23 will not move downwardly in the direction of the fill openings 15 in the tubes to provide a sterilization effect on the openings of the tubes or containers. In contrast, both the method of claim 12 and the device of claim 24 require conveying a sterile medium in a direction of the filler opening from the sterile barrier by the media delivery device or the media deliverer. Such method step and such structure are not disclosed or rendered obvious by the German Hansen patent, when considered alone or in combination with any of the other cited patent documents." (emphasis added),

this is not found persuasive for the following reasons:

Firstly, the argument that the heated air does not provide a sterilization effect on the opening of the tubes opening is mere speculation, because it is not supported by the disclosure. On the contrary, Hansen et al. (US 2004/0065983 A1) clearly discloses the following:

"The sterile barrier is in the form of a heatable plate movable together with the separating element severing the tube, the plate being heated to a germ-killing temperature, preferably above 150° C. In that the plate moves with the cutting edge severing the tube, the fill opening is covered by the heated plate even as the tube is being formed, that is, at no time is the fill opening uncovered." ([0007]).

Secondly, it is construed that as the heated plate or sterile barrier (23) being heated to the "germ-killing" temperature, the air surrounding of the heated plate also being heated, and because the heat source is on going (continuously), the surrounding

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air also being heated continuously. As one clearly sees that, as the result, the heated air of the surrounding of the heated plate is expanding continuously, propagating to continuously replacing the surrounding cool air and cover the area surrounding the mold, and thus protecting (sterilizing) the fill opening (15).

Finally, Hansen et al. (US 2004/0065983 A1) clearly discloses that the sterile medium is being conveyed to cover the filler opening:

"A cost-effective process with short cycle times is obtained if the heatable plate with the cutting edge for severance of the tube mounted on its leading edge is moved from a retracted initial position to an operating position in a direction in which the plate is mounted above the path of movement of the mould leading into the filling position, in such a way that the fill opening is covered by the plate throughout its travel to the filling position, and so that plate and cutting edge are then moved back from the operating position to the initial position after the mould has reached the filling position." ([0009]).

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to THANH K. TRUONG whose telephone number is (571)272-4472. The examiner can normally be reached on Mon-Fri 9:00AM - 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi Rada can be reached on 571-272-4467. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

tkk
August 11, 2008.

/Thanh K Truong/
Primary Examiner, Art Unit 3721.